

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

SANOFI-AVENTIS and	)	
SANOFI-AVENTIS U.S. LLC,	)	
	)	
Plaintiffs/Counterclaim Defendants	)	
	)	
v.	)	
	)	
ACTAVIS SOUTH ATLANTIC LLC,	)	
AUROBINDO PHARMA LTD.,	)	
MYLAN PHARMACEUTICALS INC.,	)	
PAR PHARMACEUTICAL, INC.,	)	
RANBAXY INC., RANBAXY	)	C. A. No. 07-572-GMS
LABORATORIES LIMITED, SUN	)	
PHARMACEUTICALS INDUSTRIES	)	
LTD., TEVA PHARMACEUTICALS	)	
USA, INC., TORRENT PHARMA INC.	)	
and TORRENT PHARMACEUTICALS	)	
LIMITED,	)	
	)	
Defendants,	)	
	)	
MYLAN PHARMACEUTICALS INC.	)	
	)	
Counterclaim Plaintiff	)	

**ANSWER, DEFENSES, AND COUNTERCLAIMS  
OF MYLAN PHARMACEUTICALS INC.**

Defendant Mylan Pharmaceuticals Inc. ("Mylan") answers the Complaint of Plaintiffs sanofi-aventis and sanofi-aventis U.S. LLC ("Plaintiffs") as follows:

**Parties**

1. Upon information and belief, Mylan admits the allegations contained in paragraph 1 of the Complaint.
2. Upon information and belief, Mylan admits the allegations contained in paragraph 2 of the Complaint.

3. Mylan lacks knowledge and information sufficient to form a belief as to the truth of the allegations contained in paragraph 3 of the Complaint and therefore denies them.

4. Mylan lacks knowledge and information sufficient to form a belief as to the truth of the allegations contained in paragraph 4 of the Complaint and therefore denies them.

5. Mylan lacks knowledge and information sufficient to form a belief as to the truth of the allegations contained in paragraph 5 of the Complaint and therefore denies them.

6. Mylan admits the allegations of paragraph 6 of the Complaint.

7. Mylan lacks knowledge and information sufficient to form a belief as to the truth of the allegations contained in paragraph 7 of the Complaint and therefore denies them.

8. Mylan lacks knowledge and information sufficient to form a belief as to the truth of the allegations contained in paragraph 8 of the Complaint and therefore denies them.

9. Mylan lacks knowledge and information sufficient to form a belief as to the truth of the allegations contained in paragraph 9 of the Complaint and therefore denies them.

10. Mylan lacks knowledge and information sufficient to form a belief as to the truth of the allegations contained in paragraph 10 of the Complaint and therefore denies them.

11. Mylan lacks knowledge and information sufficient to form a belief as to the truth of the allegations contained in paragraph 11 of the Complaint and therefore denies them.

12. Mylan lacks knowledge and information sufficient to form a belief as to the truth of the allegations contained in paragraph 12 of the Complaint and therefore denies them.

13. Mylan lacks knowledge and information sufficient to form a belief as to the truth of the allegations contained in paragraph 13 of the Complaint and therefore denies them.

14. Mylan lacks knowledge and information sufficient to form a belief as to the truth of the allegations contained in paragraph 14 of the Complaint and therefore denies them.

**Nature of the Action**

15. Mylan admits that Plaintiffs purport to bring this action for the alleged infringement of United States Patent No. 4,661,491 (“the ‘491 patent”) and United States Patent No. 6,149,940 (“the ‘940 patent”) and that copies of the ‘491 patent and the ‘940 patent appear to be attached to the Complaint as Exhibits A and B. Mylan also admits that Plaintiffs purport to bring this action based upon the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*

**Jurisdiction and Venue**

16. Mylan admits that the Court has subject matter jurisdiction over the claims in this action.

17. For the purposes of this action, Mylan does not contest the Court’s jurisdiction over Mylan. Mylan denies that it “has committed, or aided, abetted, contributed to and/or participated in the commission of, the tortious act of patent infringement that has led to foreseeable harm and injury to a Delaware company, Plaintiff sanofi-aventis U.S.” Mylan lacks knowledge and information sufficient to form a belief as to the truth of the allegations contained in the remaining allegations of paragraph 17 of the Complaint and therefore denies them.

18. Mylan lacks knowledge and information sufficient to form a belief as to the truth of the allegations contained in paragraph 18 of the Complaint and therefore denies them.

19. Mylan lacks knowledge and information sufficient to form a belief as to the truth of the allegations contained in paragraph 19 of the Complaint and therefore denies them.

20. Mylan lacks knowledge and information sufficient to form a belief as to the truth of the allegations contained in paragraph 20 of the Complaint and therefore denies them.

21. For the purposes of this action, Mylan does not contest the Court’s jurisdiction over Mylan.

22. Mylan lacks knowledge and information sufficient to form a belief as to the truth of the allegations contained in paragraph 22 of the Complaint and therefore denies them.

23. Mylan lacks knowledge and information sufficient to form a belief as to the truth of the allegations contained in paragraph 23 of the Complaint and therefore denies them.

24. Mylan lacks knowledge and information sufficient to form a belief as to the truth of the allegations contained in paragraph 24 of the Complaint and therefore denies them.

25. Mylan lacks knowledge and information sufficient to form a belief as to the truth of the allegations contained in paragraph 25 of the Complaint and therefore denies them.

26. Mylan lacks knowledge and information sufficient to form a belief as to the truth of the allegations contained in paragraph 26 of the Complaint and therefore denies them.

27. Mylan lacks knowledge and information sufficient to form a belief as to the truth of the allegations contained in paragraph 27 of the Complaint and therefore denies them.

28. Mylan lacks knowledge and information sufficient to form a belief as to the truth of the allegations contained in paragraph 28 of the Complaint and therefore denies them.

29. Mylan lacks knowledge and information sufficient to form a belief as to the truth of the allegations contained in paragraph 29 of the Complaint and therefore denies them.

30. Mylan does not contest venue in this judicial district as to Mylan, but specifically denies that this judicial district is the most appropriate and convenient venue for this action. Mylan lacks knowledge and information to form a belief as to the truth of the remaining allegations contained in paragraph 30 of the Complaint regarding other defendants and therefore denies them.

### **The Patents**

31. Mylan admits that the '491 patent, titled "Alfuzosine Compositions and Use," purports to have issued on April 28, 1987, and that Plaintiff sanofi-aventis is indicated in the records of the U.S. Patent and Trademark Office ("USPTO") as the owner or assignee of the '491 patent. Mylan denies that the '491 patent was duly and legally issued. Mylan admits that Plaintiff sanofi-aventis U.S. LLC is indicated in the records of the FDA as the holder of New Drug Application #21-287 for Uroxatral<sup>®</sup> brand alfuzosin hydrochloride extended release tablets and that the '491 patent is listed in the *Approved Drug Products with Therapeutic Equivalence Evaluations* ("the Orange Book") for Uroxatral<sup>®</sup>. Mylan lacks sufficient information to form a belief regarding the remaining allegations in paragraph 31 of the Complaint and therefore denies them.

32. Mylan admits that the '940 patent, titled "Tablet with Controlled Release of Alfuzosine Chlorhydrate," purports to have issued on November 21, 2000, and that Plaintiff sanofi-aventis is indicated in the records of the USPTO as the co-owner, or co-assignee, of the '940 patent along with Jagotec AG. Mylan further admits that the '940 patent is listed in the Orange Book for Uroxatral<sup>®</sup>. Mylan lacks sufficient information to form a belief regarding the remaining allegations in paragraph 32 of the Complaint and therefore denies the same.

### **Acts Giving Rise to this Action**

#### **Count I – Infringement of the '491 Patent by Defendants Actavis and Par**

33. Mylan lacks knowledge and information sufficient to form a belief as to the truth of the allegations contained in paragraph 33 of the Complaint and therefore denies them.

34. Mylan lacks knowledge and information sufficient to form a belief as to the truth of the allegations contained in paragraph 34 of the Complaint and therefore denies them.

35. Mylan lacks knowledge and information sufficient to form a belief as to the truth of the allegations contained in paragraph 35 of the Complaint and therefore denies them.

36. Mylan lacks knowledge and information sufficient to form a belief as to the truth of the allegations contained in paragraph 36 of the Complaint and therefore denies them.

37. Mylan lacks knowledge and information sufficient to form a belief as to the truth of the allegations contained in paragraph 37 of the Complaint and therefore denies them.

38. Mylan lacks knowledge and information sufficient to form a belief as to the truth of the allegations contained in paragraph 38 of the Complaint and therefore denies them.

39. Mylan lacks knowledge and information sufficient to form a belief as to the truth of the allegations contained in paragraph 39 of the Complaint and therefore denies them.

**Count II – Infringement of the ‘940 Patent by Defendants Actavis and Par**

40. Mylan lacks knowledge and information sufficient to form a belief as to the truth of the allegations contained in paragraph 40 of the Complaint and therefore denies them.

41. Mylan lacks knowledge and information sufficient to form a belief as to the truth of the allegations contained in paragraph 41 of the Complaint and therefore denies them.

42. Mylan lacks knowledge and information sufficient to form a belief as to the truth of the allegations contained in paragraph 42 of the Complaint and therefore denies them.

43. Mylan lacks knowledge and information sufficient to form a belief as to the truth of the allegations contained in paragraph 43 of the Complaint and therefore denies them.

44. Mylan lacks knowledge and information sufficient to form a belief as to the truth of the allegations contained in paragraph 44 of the Complaint and therefore denies them.

45. Mylan lacks knowledge and information sufficient to form a belief as to the truth of the allegations contained in paragraph 45 of the Complaint and therefore denies them.

46. Mylan lacks knowledge and information sufficient to form a belief as to the truth of the allegations contained in paragraph 46 of the Complaint and therefore denies them.

**Count III – Infringement of the ‘491 Patent by Defendants  
Aurobindo Ltd. and Aurobindo Inc.**

47. Mylan lacks knowledge and information sufficient to form a belief as to the truth of the allegations contained in paragraph 47 of the Complaint and therefore denies them.

48. Mylan lacks knowledge and information sufficient to form a belief as to the truth of the allegations contained in paragraph 48 of the Complaint and therefore denies them.

49. Mylan lacks knowledge and information sufficient to form a belief as to the truth of the allegations contained in paragraph 49 of the Complaint and therefore denies them.

50. Mylan lacks knowledge and information sufficient to form a belief as to the truth of the allegations contained in paragraph 50 of the Complaint and therefore denies them.

51. Mylan lacks knowledge and information sufficient to form a belief as to the truth of the allegations contained in paragraph 51 of the Complaint and therefore denies them.

52. Mylan lacks knowledge and information sufficient to form a belief as to the truth of the allegations contained in paragraph 52 of the Complaint and therefore denies them.

53. Mylan lacks knowledge and information sufficient to form a belief as to the truth of the allegations contained in paragraph 53 of the Complaint and therefore denies them.

**Count IV – Infringement of the ‘940 Patent by Defendants  
Aurobindo Ltd. and Aurobindo Inc.**

54. Mylan lacks knowledge and information sufficient to form a belief as to the truth of the allegations contained in paragraph 54 of the Complaint and therefore denies them.

55. Mylan lacks knowledge and information sufficient to form a belief as to the truth of the allegations contained in paragraph 55 of the Complaint and therefore denies them.



56. Mylan lacks knowledge and information sufficient to form a belief as to the truth of the allegations contained in paragraph 56 of the Complaint and therefore denies them.

57. Mylan lacks knowledge and information sufficient to form a belief as to the truth of the allegations contained in paragraph 57 of the Complaint and therefore denies them.

58. Mylan lacks knowledge and information sufficient to form a belief as to the truth of the allegations contained in paragraph 58 of the Complaint and therefore denies them.

59. Mylan lacks knowledge and information sufficient to form a belief as to the truth of the allegations contained in paragraph 59 of the Complaint and therefore denies them.

60. Mylan lacks knowledge and information sufficient to form a belief as to the truth of the allegations contained in paragraph 60 of the Complaint and therefore denies them.

**Count V – Infringement of the ‘491 Patent by Defendant Mylan**

61. Mylan admits that it filed its ANDA No. 79-014 with the FDA seeking approval for generic Alfuzosin Hydrochloride Extended-release Tablets in 10 mg strength; and that the content of Mylan’s ANDA speaks for itself.

62. Mylan admits that it provided Plaintiffs with Mylan’s notice of its ANDA No. 79-014; that Plaintiffs received such notice on or about August 27, 2007; that such notice satisfied all statutory and regulatory requirements; and that the content of that notice speaks for itself.

63. The allegations contained in paragraph 63 of the Complaint are legal conclusions to which no response is required. To the extent that a response is required, Mylan denies the allegations of paragraph 63 of the Complaint.

64. The allegations contained in paragraph 64 of the Complaint are legal conclusions to which no response is required. To the extent that a response is required, Mylan denies the allegations of paragraph 64 of the Complaint.



65. The allegations contained in paragraph 65 of the Complaint are legal conclusions to which no response is required. To the extent that a response is required, Mylan denies the allegations of paragraph 65 of the Complaint.

**Count VI – Infringement of the ‘940 Patent by Defendant Mylan**

66. Mylan admits that it filed its ANDA No. 79-014 with the FDA seeking approval for generic Alfuzosin Hydrochloride Extended-release Tablets in 10 mg strength; and that the content of Mylan’s ANDA speaks for itself.

67. Mylan admits that it provided Plaintiffs with Mylan’s notice of its ANDA No. 79-014; that Plaintiffs received such notice on or about August 27, 2007; that such notice satisfied all statutory and regulatory requirements; and that the content of that notice speaks for itself.

68. The allegations contained in paragraph 68 of the Complaint are legal conclusions to which no response is required. To the extent that a response is required, Mylan denies the allegations of paragraph 68 of the Complaint.

69. The allegations contained in paragraph 69 of the Complaint are legal conclusions to which no response is required. To the extent that a response is required, Mylan denies the allegations of paragraph 69 of the Complaint.

70. The allegations contained in paragraph 70 of the Complaint are legal conclusions to which no response is required. To the extent that a response is required, Mylan denies the allegations of paragraph 70 of the Complaint.

**Count VII – Infringement of the ‘940 Patent by Defendants  
Ranbaxy Ltd. and Ranbaxy Inc.**

71. Mylan lacks knowledge and information sufficient to form a belief as to the truth of the allegations contained in paragraph 71 of the Complaint and therefore denies them.

72. Mylan lacks knowledge and information sufficient to form a belief as to the truth of the allegations contained in paragraph 72 of the Complaint and therefore denies them.

73. Mylan lacks knowledge and information sufficient to form a belief as to the truth of the allegations contained in paragraph 73 of the Complaint and therefore denies them.

74. Mylan lacks knowledge and information sufficient to form a belief as to the truth of the allegations contained in paragraph 74 of the Complaint and therefore denies them.

75. Mylan lacks knowledge and information sufficient to form a belief as to the truth of the allegations contained in paragraph 75 of the Complaint and therefore denies them.

76. Mylan lacks knowledge and information sufficient to form a belief as to the truth of the allegations contained in paragraph 76 of the Complaint and therefore denies them.

77. Mylan lacks knowledge and information sufficient to form a belief as to the truth of the allegations contained in paragraph 77 of the Complaint and therefore denies them.

**Count VIII – Infringement of the ‘940 Patent by Defendants Sun Inc. and Sun Ltd.**

78. Mylan lacks knowledge and information sufficient to form a belief as to the truth of the allegations contained in paragraph 78 of the Complaint and therefore denies them.

79. Mylan lacks knowledge and information sufficient to form a belief as to the truth of the allegations contained in paragraph 79 of the Complaint and therefore denies them.

80. Mylan lacks knowledge and information sufficient to form a belief as to the truth of the allegations contained in paragraph 80 of the Complaint and therefore denies them.

81. Mylan lacks knowledge and information sufficient to form a belief as to the truth of the allegations contained in paragraph 81 of the Complaint and therefore denies them.

82. Mylan lacks knowledge and information sufficient to form a belief as to the truth of the allegations contained in paragraph 82 of the Complaint and therefore denies them.

83. Mylan lacks knowledge and information sufficient to form a belief as to the truth of the allegations contained in paragraph 83 of the Complaint and therefore denies them.

84. Mylan lacks knowledge and information sufficient to form a belief as to the truth of the allegations contained in paragraph 84 of the Complaint and therefore denies them.

**Count IX Infringement of the '491 Patent by Defendant Teva**

85. Mylan lacks knowledge and information sufficient to form a belief as to the truth of the allegations contained in paragraph 85 of the Complaint and therefore denies them.

86. Mylan lacks knowledge and information sufficient to form a belief as to the truth of the allegations contained in paragraph 86 of the Complaint and therefore denies them.

87. Mylan lacks knowledge and information sufficient to form a belief as to the truth of the allegations contained in paragraph 87 of the Complaint and therefore denies them.

88. Mylan lacks knowledge and information sufficient to form a belief as to the truth of the allegations contained in paragraph 88 of the Complaint and therefore denies them.

89. Mylan lacks knowledge and information sufficient to form a belief as to the truth of the allegations contained in paragraph 89 of the Complaint and therefore denies them.

**Count X – Infringement of the '940 Patent by Defendant Teva**

90. Mylan lacks knowledge and information sufficient to form a belief as to the truth of the allegations contained in paragraph 90 of the Complaint and therefore denies them.

91. Mylan lacks knowledge and information sufficient to form a belief as to the truth of the allegations contained in paragraph 91 of the Complaint and therefore denies them.

92. Mylan lacks knowledge and information sufficient to form a belief as to the truth of the allegations contained in paragraph 92 of the Complaint and therefore denies them.

93. Mylan lacks knowledge and information sufficient to form a belief as to the truth of the allegations contained in paragraph 93 of the Complaint and therefore denies them.

94. Mylan lacks knowledge and information sufficient to form a belief as to the truth of the allegations contained in paragraph 94 of the Complaint and therefore denies them.

**Count XI – Infringement of the ‘491 Patent by Defendants Torrent Ltd. and Torrent Inc.**

95. Mylan lacks knowledge and information sufficient to form a belief as to the truth of the allegations contained in paragraph 95 of the Complaint and therefore denies them.

96. Mylan lacks knowledge and information sufficient to form a belief as to the truth of the allegations contained in paragraph 96 of the Complaint and therefore denies them.

97. Mylan lacks knowledge and information sufficient to form a belief as to the truth of the allegations contained in paragraph 97 of the Complaint and therefore denies them.

98. Mylan lacks knowledge and information sufficient to form a belief as to the truth of the allegations contained in paragraph 98 of the Complaint and therefore denies them.

99. Mylan lacks knowledge and information sufficient to form a belief as to the truth of the allegations contained in paragraph 99 of the Complaint and therefore denies them.

100. Mylan lacks knowledge and information sufficient to form a belief as to the truth of the allegations contained in paragraph 100 of the Complaint and therefore denies them.

101. Mylan lacks knowledge and information sufficient to form a belief as to the truth of the allegations contained in paragraph 101 of the Complaint and therefore denies them.

**Count XII – Infringement of the ‘940 Patent by Defendants Torrent Ltd. and Torrent, Inc.**

102. Mylan lacks knowledge and information sufficient to form a belief as to the truth of the allegations contained in paragraph 102 of the Complaint and therefore denies them.

103. Mylan lacks knowledge and information sufficient to form a belief as to the truth of the allegations contained in paragraph 103 of the Complaint and therefore denies them.

104. Mylan lacks knowledge and information sufficient to form a belief as to the truth of the allegations contained in paragraph 104 of the Complaint and therefore denies them.

105. Mylan lacks knowledge and information sufficient to form a belief as to the truth of the allegations contained in paragraph 105 of the Complaint and therefore denies them.

106. Mylan lacks knowledge and information sufficient to form a belief as to the truth of the allegations contained in paragraph 106 of the Complaint and therefore denies them.

107. Mylan lacks knowledge and information sufficient to form a belief as to the truth of the allegations contained in paragraph 107 of the Complaint and therefore denies them.

108. Mylan lacks knowledge and information sufficient to form a belief as to the truth of the allegations contained in paragraph 108 of the Complaint and therefore denies them.

#### **GENERAL DENIAL**

Any allegation in Plaintiffs' Complaint not expressly admitted by Defendant Mylan is hereby denied. Having answered Plaintiffs' Complaint, Mylan denies that Plaintiffs are entitled to the relief requested in Plaintiffs' Prayer for Relief or to any relief whatsoever.

#### **DEFENSES**

Without prejudice to the denials set forth in its Answer to the Complaint, and without admitting any allegations of the Complaint not otherwise admitted, Mylan asserts the following defenses to the Complaint:

### **FIRST DEFENSE**

The manufacture, use, or sale of the product that is the subject of Mylan's ANDA No. 79-014 ("the Mylan Product") has not infringed, does not infringe, and would not, if marketed, infringe one or more claims of the '940 patent, either literally or under the doctrine of equivalents.

### **SECOND DEFENSE**

The claims of the '491 patent are invalid for failure to satisfy one or more of the conditions for patentability contained in 35 U.S.C. §§102, 103 and/or 112.

### **THIRD DEFENSE**

By virtue of the prosecution proceedings before the United States Patent and Trademark Office of the patent application leading to the '940 patent, Plaintiffs are estopped from maintaining that any claim of the '940 patent is infringed under the doctrine of equivalents by the Mylan Product.

### **FOURTH DEFENSE**

Because sanofi-aventis is merely a co-owner of the '940 patent, sanofi-aventis lacks standing to bring an action for patent infringement of the '940 patent for failing to join Jagotec AG, the additional co-owner of the '940 patent.

### **FIFTH DEFENSE**

Any and all additional defenses and counterclaims that discovery may reveal.

### **COUNTERCLAIMS**

For its counterclaims against Plaintiffs/Counterclaim Defendants sanofi-aventis and sanofi-aventis U.S. LLC ("Counterclaim Defendants"), Defendant/Counterclaim Plaintiff Mylan Pharmaceuticals Inc. ("Mylan") states as follows:

**PARTIES**

1. Upon information and belief, Counterclaim Defendant sanofi-aventis is a corporation organized and existing under the laws of France, having its principal place of business at 174 avenue de France, Paris, France 75013.

2. Upon information and belief, Counterclaim Defendant sanofi-aventis U.S. LLC is a limited liability company organized and existing under the laws of Delaware with its North American headquarters located at 55 Corporate Drive, Bridgewater, New Jersey 08807.

3. Mylan is a corporation organized under the laws of the State of West Virginia, having its headquarters at 781 Chestnut Ridge Road, Morgantown, West Virginia 26504.

**JURISDICTION AND VENUE**

4. These counterclaims arise under the Patent Laws of the United States, 35 U.S.C. § 100 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

5. The Court has original jurisdiction over the subject matter of these counterclaims pursuant to 28 U.S.C. §§ 1331 and 1338(a).

6. The Court has personal jurisdiction over Counterclaim Defendants because Counterclaim Defendants have availed themselves of the rights and privileges of this forum by suing Mylan in this judicial District; because Counterclaim Defendant sanofi-aventis U.S. LLC is a subsidiary of Counterclaim Defendant sanofi-aventis and a Delaware Limited Liability Company; and because of Counterclaim Defendants' systematic and continuous contacts with Delaware by virtue of sanofi-aventis U.S. LLC's distribution of drugs for sale and use in Delaware.

7. Venue for these Counterclaims is proper in this judicial District pursuant to 28 U.S.C. §§ 1391(b) and 1400(b).



**PATENTS IN SUIT**

8. On or about April 28, 1987, the United States Patent and Trademark Office (“USPTO”) issued United States Patent No. 4,661,491 (“the ‘491 patent”), entitled “Alfuzosine Compositions and Use.” Counterclaim Defendant sanofi-aventis is indicated in the records of the USPTO as the owner or assignee of the ‘491 patent.

9. On or about November 21, 2000, the USPTO issued United States Patent No. 6,149,940 (“the ‘940 patent”), entitled “Tablet with Controlled Release of Alfuzosine Chlorhydrate.” Counterclaim Defendant sanofi-aventis is indicated in the records of the USPTO as the co-owner, or co-assignee, of the ‘940 patent along with Jagotec AG. Upon information and belief, sanofi-aventis holds an exclusive license to Jagotec AG’s interests in the ‘940 patent.

10. Counterclaim Defendant sanofi-aventis U.S. LLC is indicated in the records of the FDA as the holder of New Drug Application #21-287 for Uroxatral® brand alfuzozin hydrochloride extended release tablets. The ‘491 patent and the ‘940 patent are listed in the *Approved Drug Products with Therapeutic Equivalence Evaluations* (“the Orange Book”) for Uroxatral®. Upon information and belief, Counterclaim defendant is the exclusive distributor of Uroxatral® in the United States.

11. On August 24, 2007, Mylan sent Counterclaim Defendants notice of its ANDA No. 79-014, which implicated the ‘491, and ‘940 patents. On August 30, 2007, Mylan also sent notice of its ANDA No. 79-014 to Jagotec AG.

12. On September 21, 2007, Counterclaim Defendants sued Mylan in this judicial District, along with several other defendants, alleging infringement of the ‘491, and ‘940 patents.

**FIRST CLAIM FOR RELIEF**

**(Declaratory Judgment of Invalidity of the '491 Patent)**

13. Mylan restates and realleges each of the foregoing paragraphs as if fully set forth herein.

14. Counterclaim Defendants have accused Mylan of infringing the '491 patent.

15. Mylan denies infringement of the '491 patent and alleges that the '491 patent is invalid for failure to comply with one or more of the requirements for patentability set forth in Title 35 of the U.S. Patent Code, including 35 U.S.C. §§ 102 and/or 103.

16. There is an actual, substantial, and continuing justiciable case or controversy between Mylan and Counterclaim Defendants regarding the infringement and validity of the '491 patent, as evidenced by Counterclaim Defendants' Complaint and Mylan's Answer and Affirmative Defenses in this action.

**SECOND CLAIM FOR RELIEF**

**(Declaratory Judgment of Non-Infringement of the '940 Patent)**

17. Mylan restates and realleges each of the foregoing paragraphs as if fully set forth herein.

18. Counterclaim Defendants have accused Mylan of infringing the '940 patent.

19. Mylan denies infringement of the '940 patent and alleges that under the doctrine of prosecution history estoppel, Counterclaim Defendants are estopped from asserting that Mylan infringes any claim of the '940 patent, either literally or under the doctrine of equivalents.

20. There is an actual, substantial, and continuing justiciable case or controversy between Mylan and Counterclaim Defendants regarding the infringement of the '940 patent, as

evidenced by Counterclaim Defendants' Complaint and Mylan's Answer and Affirmative Defenses in this action.

**PRAYER FOR RELIEF**

WHEREFORE, Mylan respectfully prays for judgment in its favor and against Plaintiffs/Counterclaim Defendants:

(a) Declaring that the manufacture, use, sale, offer for sale, or importation of the drug products that are the subject of Mylan's ANDA No. 79-014 have not infringed, do not infringe and would not, if manufactured, used, sold offered for sale, or imported, directly infringe any valid or enforceable claim of the '491 and '940 patents, either literally or under the doctrine of equivalents, by inducement of infringement, or otherwise;

(b) Declaring that Mylan has not willfully infringed any claim of the '491, and '940 patents;

(c) Declaring that the claims of the '491 and '940 patents are invalid;

(d) Ordering that Plaintiffs/Counterclaim Defendants' Complaint be dismissed with prejudice and judgment entered in favor of Mylan;

(e) Declaring this case exceptional and awarding Mylan its reasonable attorney's fees and costs of these Counterclaims pursuant to 35 U.S.C. §285; and

(f) Awarding Mylan such other and further relief as the Court may deem just and proper.

Respectfully submitted,

OF COUNSEL:

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Dated: October 15, 2007  
825471 / 30582

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*Attorneys for Defendant*  
*Mylan Pharmaceuticals Inc.*

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

CERTIFICATE OF SERVICE

I, Richard L. Horwitz, hereby certify that on October 15, 2007, the attached document was electronically filed with the Clerk of the Court using CM/ECF which will send notification to the registered attorney(s) of record that the document has been filed and is available for viewing and downloading.

I further certify that on October 15, 2007, I have Electronically Mailed the document to the following person(s):

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